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K041137

Special 510(k) Summary

April 28, 2004

This 510(k) Summary has been prepared by the following submitter (who also acts as the United States Distributor of the NewTom model QR-DVT 9000):

Address and Registration Number of Submitter/Distributor:
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Contact: K. Robert Wisner, Esq.
Distributor's Registration Number: 2438913

Address and Registration # of the Manufacturer:
NIM S.r.l.
Via Silvestrini 20
Verona, Italy
37135
Manufacturer's FDA Registration #: 3003310161

Device Trade Name:
NewTom 3G model QR-DVT 9000

Common/Classification Name:
Computed Tomography X-ray System

Predicate Device Information:
The predicate device is the NewTom model QR-DVT 9000 Computed Tomography X-ray System, [510(k) # K003787] this predicate device has been has been classified as Class II, 90 JAA/ 90MUH. The NewTom 3G model QR-DVT 9000 is substantially equivalent to the NewTom model QR-DVT 9000.

Device Description and Intended Use:
The device description of the NewTom 3G model QR-DVT 9000 Computed Tomography X-ray System is as follows:

> The NewTom 3G is a dedicated X-Ray imaging device that uses an X-Ray imaging system and a patient table. The NewTom 3G acquires a 360-degree rotational X-Ray sequence, reconstructs a three-dimensional matrix of the examined volume and produces two-dimensional views of this volume,

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displaying both two- and three-dimensional images. The NewTom 3G can measure distances and thickness on two-dimensional images.

Images produced by the NewTom 3G can be printed or exported on magnetic and optical media.

The NewTom 3G is designed for use in diagnostic support both in odontoiatric radiology, with a particular reference to "planning" and to monitoring of implantations, and in the field of maxillofacial surgery.

The NewTom 3G hardware, including a patient table and a gantry (comprised of an X-ray Source, image chain and a motorized arm) facilitates the acquisition of a full X-Ray sequence by the device's software. The NewTom software runs either in a Windows 2K or Windows XP workstation.

The NewTom 3G is an X-Ray imaging device that constructs a three-dimensional model from images taken during a rotational X-Ray sequence. The NewTom 3G is optimized for bone morphology analysis on the maxillofacial region.

The NewTom 3G reconstructs a three-dimensional model for X-Ray images similar to the three-dimensional model obtained using the original NewTom X-Ray system.

Comparison of Technological Characteristics with the Predicate Device:

The NewTom 3G model QR-DVT 9000 Computed Tomography X-ray System is a dedicated X-Ray imaging device that acquires a 360-degree rotational X-Ray sequence for use in diagnostic support in odontoiatric radiology (with a particular reference to patient evaluation and the monitoring of implantations) and in the field of maxillofacial surgery. This is the **same intended use** as previously cleared for the NewTom model QR-DVT 9000 Computed Tomography X-ray System, [510 (k) #K003787].

Further, the NewTom 3G model QR-DVT 9000 is substantially similar to the NewTom model QR-DVT 9000 which previously received 510(k) concurrence in the following ways, both machines:

- have the same indicated use;
- use the same operating principle;
- incorporate the same basic technology;
- incorporate the same materials.

The determination of substantial equivalence of the predicate device has been based upon the comparison of machine specifications and not upon clinical and/or non-clinical performance data, thus 21 C.F.R. Part 807.92(b) does not apply.

Conclusion: K041137

The NewTom 3G model QR-DVT 9000 acquires an X-ray rotational sequence and provides three-dimensional information on the analyzed volume. The potential hazards (e.g., electrical, mechanical, thermal, radiation, incorrect measurement and misdiagnosis) are controlled by the NewTom's risk management system including:

- A hazard analysis performed according to a fault tree which indicates an extremely low probability of harmful events;
- A hardware an software development and validation process under EN 46001-ISO 13485 quality system;
- Adherence to International Standards- International Electrotechnical Commission (IEC); and
- Adherence to U.S. Standards 21 CFR 1020.33.

The NewTom 3G model QR-DVT 9000 is an x-ray imaging system that complies with requirements of 21 C.F.R. Part 807.87(h), and does not pose any new safety risks or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

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AUG 23 2013

Re: K041137
Trade/Device Name: NewTom 3G QR-DVT 9000
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: April 28, 2004
Received: April 30, 2004

Dear Mr. Wisner:

This letter corrects our substantially equivalent letter of May 14, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

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Indications for Use Statement

510(k) Number:

The original NewTom QR-DVT 9000 (predicate device) 510(k) Number is: K003787. The NewTom 3G QR-DVT 9000 number is not yet available.

Device Name:

NewTom 3G QR-DVT 9000 Computed Tomography X-ray System

Indications for Use:

The NewTom QR-DVT 9000 Computed Tomography X-ray System is a dedicated X-Ray imaging device that acquires a 360-degree rotational X-Ray sequence for use in diagnostic support in odontoiatric radiology (with a particular reference to patient evaluation and the monitoring of implantations) and in the field of maxillofacial surgery. This is the **same intended use** as previously cleared for the NewTom QR-DVT 9000 Computed Tomography X-ray System, [510 (k) #K003787].

The NewTom QR-DVT 9000 accomplishes this task by reconstructing a three-dimensional matrix of the examined volume and producing two-dimensional views of this volume, displaying both two- and three-dimensional images.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801. 109)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041137